EXHIBIT N

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA – WESTERN DIVISION

NEUROGRAFIX, a California corporation; WASHINGTON RESEARCH FOUNDATION, a not-for-profit Washington corporation, Plaintiffs, vs. SIEMENS MEDICAL SOLUTIONS USA, INC., a Delaware corporation; and SIEMENS AKTIENGESELLSCHAFT, a German corporation, Defendants.	Case No. 10-CV-1990 MRP (RZx) [Assigned to The Honorable Mariana R. Pfaelzer] **REBUTTAL EXPERT REPORT OF MICHAEL E. MOSELEY PHD CONCERNING U.S. PATENT NO. 5,560,360**
SIEMENS MEDICAL SOLUTIONS USA, INC., Counterclaimant, vs. NEUROGRAFIX, and WASHINGTON RESEARCH FOUNDATION Counterdefendants.	

REBUTTAL EXPERT REPORT OF MICHAEL E. MOSELEY PHD CONCERNING U.S. PATENT NO. 5,560,360

1. I have been asked to render an opinion regarding certain phrases in the claims of U.S. Patent No. 5,560,360 ("the '360 patent"), and if called upon to testify, intend to testify to the opinions disclosed herein.

2. I reserve the right to respond to any rebuttal that Plaintiffs offer in response to these opinions. I also reserve the right to supplement my opinions if Plaintiffs change their proposed claim constructions.

I. Background and Qualifications

3. I have been a Professor of Radiology in the Radiological Sciences Laboratory at Stanford University for the last 17 years. In that position, I have focused on experimental and clinical neuroscience research using MRI and have collaborations within the Departments of Radiology, Neurology, Neurosurgery, and other groups at Stanford University and internationally. I serve on several editorial boards, including the Journal of MRI. I am also active in various magnetic resonance ("MR") societies, including the International Society of Magnetic Resonance in Medicine ("ISMRM"). I am a Fellow of ISMRM, a Past President of the ISMRM, and in 2001 I was awarded the ISMRM Gold Medal for pioneering research in diffusion MRI. Most recently I was elected an honorary lifetime member of the Society for MR Technologists. Prior to my work at Stanford University, I earned my PhD in biophysical NMR from Uppsala University in Sweden, and from 1982 through 1993 I was a faculty member in Radiology and conducted research at the University of California at San Francisco, focusing on MRI physics and diffusion MRI. My complete CV was attached as Exhibit A to my January 24th report. I am being compensated $300 per hour, which is my customary rate.

II. Materials Considered

4. In reaching the opinions herein, I have considered the '360 patent, the history of its prosecution before the USPTO, and the prior art cited in the USPTO. I have also considered

my experience in magnetic resonance, including my experience in imaging physics, tissue contrast mechanisms, and image processing and analysis. I have also considered Dr. Filler's January 24th report submitted by Plaintiffs and the documents and references cited therein or in Exhibit A to Dr. Filler's report. I have also considered NeuroGrafix's infringement contentions, NeuroGrafix's proposed claim constructions, and the documents, images, and software cited and/or discussed in this report or in the exhibits to this report.

III. Claim Construction

5. I understand that the parties agree that the claim limitations discussed in Dr. Filler's January 24th report, which are discussed herein, are written in a "means-plus-function" format, which requires a particular claim construction analysis. I also understand that for each means-plus-function claim limitation, it is necessary to identify the claimed function, as well as the corresponding structure or act described in the specification that is clearly linked in the specification to performing that function and necessary to perform that function.

IV. Claim Analysis

A. "processor means" limitations in claims 54, 55, 58, 61, and 64

6. As discussed in more detail below with respect to the specific claims, claims 54, 55, 58, 61, and 64 each include a "processor means" limitation for performing various functions related to generating various data sets.

7. These functions would be implemented by a computer programmed with a particular algorithm or instructions to perform each respective function.

8. It appears Dr. Filler agrees that these functions are implemented by a computer, as his report points to the computer 72, front-end circuit 74, and host processing system 32 as the structures that he believes performs each of the relevant functions in claims 54, 55, 58, 61, and 64. (Filler Report ¶81 (claim 54), ¶99 (claim 55), ¶115 (claim 64), ¶127 (claims 58 and 61).)

The specification discloses that the computer 72 is simply a computer, stating that it could be, "for example, an IBM-compatible personal computer including a 486 processor, VGA monitor, and keyboard." ('360 patent 11:15-17.) The host processing system is also simply a computer according to the specification. For instance, the specification states that "system 32 includes a central processing unit (CPU)." ('360 patent 9:45-46.)

9. Dr. Filler's report also indicates that, to achieve these various functions, the computer would need to be programmed with an algorithm that performs the recited function, because his report identifies what he refers to as "examples" of the algorithms that could perform these functions. (*See, e.g.*, Filler Report ¶75 (claim 54), ¶¶88, 93, 94 (claim 55), ¶¶105, 111 (claim 64), ¶123 (claims 58 and 61).) Instructions, described by an algorithm, flowchart, or software instructions are, in my opinion, necessary to achieve the recited functions for the "processor means" in claims 54, 55, 58, 61, and 64. Disclosing simply that a computer could perform the recited function does not, by itself, convey a precise description to a person of skill in the art as to how the computer would perform the function. Rather, to convey to a person of skill in the art the precise scope of these "processor means" claim limitations, the specification would need to disclose and clearly link a particular computer algorithm, flowchart, or software instructions that the computer 72 or host processing system 32 should be programmed with to perform the recited function.

10. Dr. Filler has not pointed to anything in the patent that describes and clearly links an algorithm, flowchart, or software instructions that could or should be used to accomplish several of the recited functions. As discussed below, the patent specification does not describe how to perform several of the recited functions and instead simply suggests that a computer could, with appropriate programming, accomplish the recited function.

11. For instance, the specification refers to some undisclosed "software instructions" being "executed" by the "host processing system" to "achieve a variety of functions":

> These components provide information to, and process information from, neurography system 10 in accordance with software instructions executed by, for example, a host processing system 32 or the processing systems of individual components of the system 12 to achieve a variety of functions beyond the imaging of peripheral nerve. ('360 patent 29:17-23.)

12. Similarly, the specification refers to the host processing system 32 as a "central processing unit" with some undisclosed set of "software instructions":

> Although not separately shown in FIG. 6, system 32 includes a central processing unit (CPU) coupled to the remainder of system 12 by input/output circuits. Memory is provided to store software instructions, used to control the operation of the CPU and, hence, the various components of system 12, and to store image and other data collected by system 12. The use of a separate host processing system 32 is particularly desirable where various components of system 12 are to be operated in interactive fashion pursuant to a single set of software instructions. ('360 patent 9:45-54.)

13. The specification also states, without describing a specific algorithm or software instructions, that:

> the computer 72 is readily able to identify nerve locations in the anatomical structure and to correctly trace the course of the nerves between two-dimensional image planes or through a three-dimensional acquisition volume. ('360 patent 21:51-54.)

14. The specification also suggests that the computer system should somehow be programmed to be an "expert" system, but the specification does not explain how someone should program the computer to make it an "expert" system, and the specification does not disclose a particular algorithm or instructions for programming the system to be "expert":

> Regardless of the routine employed to project the neural structure in three-dimensions, the system 10 may be further programmed to implement the projection by referring to known characteristics of the structure. More particularly, once a given nerve has been identified in a given two-dimensional image, an "expert" system 10 is able to predict the occurrence of certain branches and mergers in this structure, albeit at unknown locations. ('360 patent 22:18-25.)

15. Without the disclosure of a definite and precise description of the algorithm, flowchart, or software instructions that perform each of the functions recited in claims 54, 55, 58, 61, and 64, a person of skill in the art would not know the precise scope of the "processor means" limitations in these claims.

16. Each of these claims is discuss below.

1. Claim 54 "processor means"

17. Claim 54 of the '360 patent refers to a "processor means." I understand that the parties agree that the function performed by the processor means in claim 54 is "processing said outputs to generate data representative of the diffusion anisotropy of the selected structure." (*See, e.g.*, Filler Report ¶67; Plaintiffs' proposed claim constructions; Defendants' proposed claim constructions.)

18. The "said outputs" recited in that function refers to the "output indicative of the resonance response" that is sensed by the excitation and output arrangement means, for each of the diffusion-weighted gradients. (*See, e.g.*, Filler Report ¶68.)

19. The function of "processing said outputs to generate data representative of the diffusion anisotropy" of a structure would be implemented by a computer programmed with a particular algorithm or instructions to perform that function.

20. It appears Dr. Filler agrees that this function is implemented by a computer, as his report points to the computer 72, front-end circuit 74, and host processing system 32 as the structures that he believes perform the relevant function. (Filler Report ¶81; *see also* Filler Report ¶51 ("computers and front-end circuits used by an MRI machine are . . . used to process the output received").)

21. Dr. Filler's report also indicates that to achieve the recited function the computer would need to be programmed with an algorithm that performs the recited function. In

particular, as discussed below, Dr. Filler's report points to what he calls an "exemplary algorithm for performing the recited functionality." (Filler Report ¶75.) Such an algorithm is, in my opinion, necessary to achieve the recited function. Disclosing simply that a computer could perform the recited function does not, by itself, convey a precise description to a person of skill in the art as to how the computer would perform the function. Rather, to convey to a person of skill in the art the precise scope of the "processor means" limitation in claim 54, the specification would need to disclose and clearly link a particular algorithm, flowchart, or software instructions with which the computer 72 or host processing system 32 should be programmed to perform the recited function of "processing said outputs to generate data representative of the diffusion anisotropy."

22. Dr. Filler's report points to blocks 112 through 128 in Figures 9 and 10 of the patent, along with the accompanying discussion in column 14, line 33 through column 15, line 31 as an "exemplary algorithm for performing the recited functionality." (Filler Report ¶75.) Dr. Filler's report refers to this implementation as "echo processing." (Filler Report ¶69 (citing '360 patent 14:32-15:31).)

23. I disagree that blocks 112 through 128 would, by themselves, be sufficient to achieve the function of "processing said outputs to generate data representative of the diffusion anisotropy." The result of performing blocks 112 through 128 would be a single diffusion coefficient ("D") for a diffusion gradient applied only in a single direction. Diffusion anisotropy is the phenomenon of water diffusing faster in some directions compared to others. A diffusion coefficient for a single applied diffusion gradient only gives information about the speed of diffusion in a single direction, and does not give any information about whether the diffusion is anisotropic or different in other directions. At a minimum, one would need to determine and

somehow compare the diffusion coefficients for at least two different diffusion gradient directions to have information or data representative of diffusion anisotropy.

24. Blocks 130 through 154 in Figure 10 show steps for calculating additional diffusion coefficients and comparing those diffusion coefficients to obtain data representative of diffusion anisotropy. The series of blocks 130, 132, 134, 136, 138, 140, 150, and 152 (for the scenario where "known axis" = "yes" in block 130) shows calculating the diffusion coefficient for two different diffusion gradient directions, one that is parallel and one that is perpendicular to the anisotropic structure of interest. The series of blocks 130, 132, 142, 144, 146, 148, 150, and 152 (for the scenario where "known axis" = "no" in block 130) shows using an iterative process to calculate diffusion coefficients for multiple different directions and determining the maximum and minimum diffusion coefficients. In either case, at blocks 150 and 152 the minimum diffusion coefficient is subtracted from the maximum diffusion coefficient to obtain a data set that is representative of anisotropic diffusion.

25. Accordingly, in addition to blocks 112 through 128, blocks 130 through 154 are also necessary for performing the function of "processing said outputs to generate data representative of the diffusion anisotropy of the selected structure." Without blocks 130 through 154, blocks 112 through 128 only provide a single diffusion coefficient representing the magnitude of diffusion in a single direction, which does not provide information or data representative of diffusion anisotropy (that is, whether diffusion is faster in one direction compared to others).

2. Claim 64: "said processor means [of claim 54] is further for"

26. Claim 64 of the '360 patent refers to the processor means of claim 54, and further requires that it performs the function of:

> processing said data representative of the diffusion anisotropy of the selected structure to produce a data set that describes the shape and position of the selected structure.

27. The "said data representative of the diffusion anisotropy" recited in that function refers to the data generated by the "processor means" functionality in claim 54, discussed above. (Filler Report ¶101.)

28. This function would be implemented by a computer programmed with an algorithm or software instructions that perform this function.

29. Dr. Filler's report lists several portions of the specification that he believes disclose examples of algorithms for performing this further functionality for the "processor means." Specifically, Dr. Filler's report refers to the following as purported examples of algorithms for performing this further function for the "processor means":

> [1] In the preferred arrangement, the images associated with the maximum and minimum values of the diffusional coefficients for a particular ROI are then used in a subtraction process, as indicated at block 152. The image associated with the larger coefficient is produced by a gradient that is more nearly perpendicular to the neural axis, enhancing the nerve image, while the image associated with the smaller coefficient is produced by a gradient that is more nearly parallel to the axis, selectively destroying the nerve signal. When these two penultimate images are then mathematically (or photographically or optically) subtracted from one another, a subtraction neurogram is produced. ('360 patent 18:35-46) (cited in Filler Report ¶105)

> [2] Also, the subtraction process can be further supplemented, if desired. For example, the output of the subtraction process can be divided by the signal information from a fat suppressed, T2-weighted spin echo sequence (e.g. using the aforementioned CHESS technique). ('360 patent 19:2-7) (cited in Filler Report ¶105)

[3] Although image subtraction is employed in the preferred arrangement, it is not necessary. For example, in some applications of known anisotropy, subtraction is unnecessary and can be foregone in favor of a threshold analysis. ('360 patent 18:66-19:2) (cited at Filler Report ¶105)

[4] Computer 72 is readily able to identify nerve locations in the anatomical structure and to correctly trace the course of the nerves between two-dimensional image planes or through a three-dimensional acquisition volume. ('360 patent 21:51-54) (cited in Filler Report ¶110)

[5] The location of nerves in a given image plane can be detected by comparing pixel intensity to some threshold level. A three-dimensional image can then be formed by linking or projecting the results of these two-dimensional analyses over the desired volume. ('360 patent 21:55-59) (cited in Filler Report ¶111)

[6] As an alternative, the vector information obtained above can be used to track continuous serial changes in the direction of maximum anisotropy of a nerve or neural tract as the nerve or tract travels along its natural course. In that regard, the direction of maximum anisotropy for each voxel associated with a nerve is determined and a voxel connection routine, of the type described in Saloner et al., Application of a Connected-Voxel Algorithm to MR Anglographic Data, 1 JOURNAL OF MAGNETIC RESONANCE IMAGING 423-430 (1991), is then used to link up voxels of maximum anisotropy. The resultant plot of the nerve or neural tract provides enhanced spatial resolution and less discontinuity from one image plane to the next. ('360 patent 21:60-22:5) (cited in Filler Report ¶111)

30. With respect to example 1, that portion of the specification simply explains how the "processor means" accomplishes the function of "processing said outputs to generate data representative of the diffusion anisotropy of the selected structure," which is the function recited in claim 54. As explained above in paragraphs 23 through 25 of this report, blocks 130 through 154 are necessary to achieve the recited function for the "processor means" in claim 54. Thus, the portion of the specification cited in example 1 above does not disclose any further algorithm beyond that which is necessary to achieve the function recited in claim 54.

31. With respect to example 3, the statement from the specification cited in Dr. Filler's report does not convey any particular algorithm for "processing said data representative of the diffusion anisotropy" to one of ordinary skill in the art, and does not disclose the precise

description for any specific algorithm for performing that function. The specification does not describe any particular algorithm or way of doing a "threshold analysis." For instance, the specification does not disclose how one performs a "threshold analysis" or even what "thresholds" to choose.

32. With respect to example 4, the statement in the specification does not convey any particular algorithm for "processing said data representative of the diffusion anisotropy" to one of ordinary skill in the art, and does not disclose the precise description for any specific algorithm for performing that function. The specification does not describe any particular algorithm or way to allow a computer to identify nerve locations and trace the course of nerves. For instance, the specification does not explain what programming or algorithm should be used so that the computer will be "readily able to identify nerve locations in the anatomical structure and to correctly trace the course of the nerves." Rather than disclosing or even suggesting an algorithm, example 4 simply restates the function of the processor means of claim 64.

33. With respect to example 5, the statement in the specification does not convey any particular algorithm for "processing said data representative of the diffusion anisotropy" to one of ordinary skill in the art, and does not disclose the precise description for any specific algorithm for performing that function. The specification does not describe any particular algorithm or way to detect the location of nerves in a given image plane by comparing pixel intensity to some threshold level and then forming a three-dimensional image by linking or projecting the results of these two-dimensional analyses over the desired volume. For instance, the specification does not disclose how one determines "some threshold level" or how one should perform "linking or projecting the results of these two-dimensional analyses over the desired volume."

34. With respect to example 6, the cited statement from the specification is just an open-ended reference to the prior art work of Saloner, et al. The statement in the specification does not convey to one of ordinary skill in the art an algorithm for, or explanation of how, "the direction of maximum anisotropy for each voxel associated with a nerve is determined," and does not disclose the precise description for any specific algorithm for performing the function recited in claim 64. Further, that reference to Saloner, et al. does not, by itself, convey to a person of skill in the art a precise description of how to implement, or an algorithm for implementing, Saloner, et al.'s work to accomplish the recited function in claim 64.

3. Claim 55 "processor means"

35. Claim 55 of the '360 patent refers to a "processor means" that performs the two subfunctions of:

> i) vector processing said outputs to generate data representative of anisotropic diffusion exhibited by the selected structure in the region, regardless of the alignment of said diffusion-weighted gradients with respect to the orientation of said selected structure; and
>
> ii) processing said data representative of anisotropic diffusion to generate a data set describing the shape and position of said selected structure in the region, said data set distinguishing said selected structure from other structures in the region that do not exhibit diffusion anisotropy.

36. These two subfunctions would be implemented by a computer programmed with particular algorithms or software instructions that perform these two subfunctions.

37. Plaintiffs appear to agree that these two subfunctions would be implemented by a computer. Dr. Filler's report notes that the "computers and front-end circuits used by an MRI machine are . . . used to process the output received." (Filler Report at ¶51.)

38. Dr. Filler's report also indicates that to achieve these recited subfunctions the computer would need to be programmed with an algorithm that performs the recited function. As explained below, for instance, Dr. Filler's report points to several portions of the specification

that he believes show "examples" of algorithms that could perform the recited subfunctions. Such an algorithm is, in my opinion, necessary to achieve the recited subfunctions. Disclosing simply that a computer could perform the recited subfunctions does not, by itself, convey a precise description to a person of skill in the art as to how the computer would perform these subfunctions. Rather, to convey to a person of skill in the art the limits of the claim, the specification would need to disclose and clearly link a particular computer algorithm, flowchart, or software instructions that the computer 72 or host processing system 32 should be programmed with to perform each of these two subfunctions recited in claim 55.

39. Each of these recited subfunctions is discussed below.

i. Subfunctionality 1: "vector processing said outputs to generate data representative of anisotropic diffusion exhibited by the selected structure in the region, regardless of the alignment of said diffusion-weighted gradients with respect to the orientation of said selected structure"

40. With respect to subfunction 1 in claim 55, Dr. Filler's report lists several portions of the specification that he believes disclose "examples of algorithms for performing subfunctionality 1." (Filler Report at ¶88.) Specifically, Dr. Filler's report (¶88) refers to the following as "examples" of algorithms for performing subfunction 1:

[1] Using equations (3), (4), (5) and (6), as described at 20:46-21:15;

[2] Using arctan, as described at 21:16-23;

[3] Using the vector analysis described in Basser et al., Fiber Orientation Mapping in an Anisotropic Medium with NMR Diffusion Spectroscopy, SMRM BOOK OF ABSTRACTS 1221 (1992), as described at 21:36-38;

[4] Using the tensor analysis employing tensors of various ranks, described in Basser et al., Diagonal and Off Diagonal Components of the Self-Diffusion Tensor: Their Relation to an Estimation from the NMR Spin-Echo Signal, SMRM BOOK OF ABSTRACTS 1222 (1992), as described at 21:39-45; and

[5] Using alternative processing techni[que] used in the evaluation of magnetic, thermal and structural anisotropy data, as described at 21:45-47.

41. With respect to examples 3 and 4 provided in Dr. Filler's report, the specification states that:

> Alternative forms of vector analysis can also be applied, for example, as described in Basser et al., Fiber Orientation Mapping in an Anisotropic Medium with NMR Diffusion Spectroscopy, SMRM BOOK OF ABSTRACTS 1221 (1992). Similarly, tensor analyses employing tensors of various ranks, as described in Basser et al., Diagonal and Off Diagonal Components of the Self-Diffusion Tensor: Their Relation to an Estimation from the NMR Spin-Echo Signal, SMRM BOOK OF ABSTRACTS 1222 (1992), can be used to treat, or transform the coordinates of, MR diffusional anisotropy data. ('360 patent 21:35-45.)

42. The cited statement from the specification is just an open-ended reference to the prior art work of Basser, et al. That reference to Dr. Basser's abstracts does not, however, by itself convey to a person of skill in the art an algorithm or description of how to apply or implement Dr. Basser's work to accomplish recited subfunction 1 in claim 55.

43. Further, Dr. Basser's abstracts describe the use of tensor modeling to characterize diffusion anisotropy, and explain a description of anisotropy that is different than calculation of a vector length (equation 3 from the patent) or diffusion vector angle (equation 4, 5, or 6 from the patent), as the patent specification describes "vector analysis." A person of skill in the art would not view Dr. Basser's abstracts as being clearly linked to the vector processing subfunction in claim 55 because Dr. Basser's abstracts do not describe calculation of diffusion vector angles as the patent describes.

44. With respect to example 5 listed in Dr. Filler's report, the patent specification states that "suitable alternative processing techniques have been developed for use in the evaluation of magnetic, thermal, and structural anisotropy data." ('360 patent 21:45-47.) That

statement does not convey any particular algorithm for "vector processing said outputs to generate data representative of anisotropic diffusion" to one of ordinary skill in the art, and does not disclose the precise description for any specific algorithm for performing subfunction 1.

ii. Subfunctionality 2: "processing said data representative of anisotropic diffusion to generate a data set describing the shape and position of said selected structure in the region, said data set distinguishing said selected structure from other structures in the region that do not exhibit diffusion anisotropy"

45. With respect to subfunction 2 in claim 55, Dr. Filler's report lists several portions of the specification that he believes disclose examples of algorithms for performing subfunctionality 2. (Filler Report at ¶¶93, 94.) Specifically, Dr. Filler's report refers to the following as examples of algorithms for performing subfunction 2:

> [1] [T]he location of nerves in a given image plane can be detected by comparing pixel intensity to some threshold level. A three-dimensional image can then be formed by linking or projecting the results of these two-dimensional analyses over the desired volume. ('360 patent 21:55-59 (cited in Filler Report ¶93).);
>
> [2] As an alternative, the vector information obtained above can be used to track continuous serial changes in the direction of maximum anisotropy of a nerve or neural tract as the nerve or tract travels along its natural course. In that regard, the direction of maximum anisotropy for each voxel associated with a nerve is determined and a voxel connection routine, of the type described in Saloner et al., Application of a Connected-Voxel Algorithm to MR Anglographic Data, 1 JOURNAL OF MAGNETIC RESONANCE IMAGING 423-430 (1991), is then used to link up voxels of maximum anisotropy. The resultant plot of the nerve or neural tract provides enhanced spatial resolution and less discontinuity from one image plane to the next. ('360 patent 21:60-22:5 (cited in Filler Report ¶94).)
>
> [3] As an alternative to the two-dimensional imaging sequences described above, it is also possible to carry out the signal acquisition using a "three dimensional" imaging sequence of the type described in Frahm et al., Rapid Three-Dimensional MR Imaging Using the FLASH Technique, 10 JOURNAL OF COMPUTER ASSISTED TOMOGRAPHY 363-368 (1986). The output of this sequence is then processed using a three-dimensional Fourier transform to extract the returns from nuclei over the volume being imaged. The resultant processing used to compute D for a given voxel and to generate, for example, a subtraction angiogram is substantially the same as described above. ('360 patent 22:6-17 (cited in Filler Report ¶94).)

46. With respect to example 1, the statement in the specification does not convey any particular algorithm for "processing said data representative of anisotropic diffusion" to one of ordinary skill in the art, and does not disclose the precise description for any specific algorithm for performing subfunction 2. The specification does not describe any particular algorithm or way to detect the location of nerves in a given image plane by comparing pixel intensity to some threshold level and then forming a three-dimensional image by linking or projecting the results of these two-dimensional analyses over the desired volume. For instance, the specification does not disclose how one determines "some threshold level" or how one should perform the "linking or projecting the results of these two-dimensional analyses over the desired volume."

47. With respect to example 2, the cited statement from the specification is just an open-ended reference to the prior art work of Saloner, et al. The statement in the specification does not convey to one of ordinary skill in the art an algorithm for, or explanation of how, "the direction of maximum anisotropy for each voxel associated with a nerve is determined," and does not disclose the precise description for any specific algorithm for performing subfunction 2. Further, that reference to Saloner, et al. does not, by itself, convey to a person of skill in the art a precise description of how to implement, or an algorithm for implementing, Saloner, et al.'s work to accomplish recited function in claim 55.

48. With respect to example 3, the cited statement from the specification is just an open-ended reference to the prior art work of Frahm, et al. The statement in the specification does not convey to one of ordinary skill in the art an algorithm for or explanation of how "to generate, for example, a subtraction angiogram." Further, the cited statement refers to a way of acquiring signal outputs, and does not disclose or explain an algorithm for processing "data representative of anisotropic diffusion" that was generated by "vector processing," but instead at

most discusses a way of acquiring signal outputs that could be processed by the processor means in claim 55. Further, that reference to Frahm, et al. does not, by itself, convey to a person of skill in the art a precise description of how to implement, or an algorithm for implementing, Saloner, et al.'s work to accomplish recited function in claim 55.

4. Claim 58/61 "said processor means [of claim 55] is further for"

49. Claims 58 and 61 of the '360 patent refer to the processor means of claim 55, and further require that it performs the function of:

> calculating a further data set that describes the three dimensional shape and position of a segment of said neural tissue by: analyzing the data representative of anisotropic diffusion to determine how to relate said data set and said additional data sets describing the shape and position of cross sections of said neural tissue; and based upon the results of said analyzing the data representative of anisotropic diffusion, combining said data set and said additional data sets to generate said further data set that describes the three dimensional shape and position of the segment of said neural tissue, thereby allowing a three dimensional shape and position of curved neural tissue to be described.

50. This function would be implemented by a computer programmed with an algorithm or software instructions that perform this function.

51. Dr. Filler's report lists several portions of the specification that he believes disclose examples of algorithms for performing this further functionality for the "processor means." Specifically, Dr. Filler's report (¶123) refers to the following as examples of algorithms for performing this further function for the "processor means":

> [1] Using equations (3), (4), (5) and (6), as described at 20:46-21:15;
>
> [2] Using arctan, as described at 21:16-23;
>
> [3] Using the vector analysis described in Basser et al., Fiber Orientation Mapping in an Anisotropic Medium with NMR Diffusion Spectroscopy, SMRM BOOK OF ABSTRACTS 1221 (1992), as described at 21:36-38;

> [4] Using the tensor analysis employing tensors of various ranks, described in Basser et al., Diagonal and Off Diagonal Components of the Self-Diffusion Tensor: Their Relation to an Estimation from the NMR Spin-Echo Signal, SMRM BOOK OF ABSTRACTS 1222 (1992), as described at 21:39-45; and
>
> [5] Using alternative processing technical used in the evaluation of magnetic, thermal and structural anisotropy data, as described at 21:45-47.

52. The examples cited by Dr. Filler's report for the three dimensional functionality are identical to the examples Dr. Filler's report says perform the function of "vector processing" in claim 55. Even if these examples were algorithms for performing some claimed function, and performing these same "algorithms" a second time would not provide a second type of data set compared to the data set generated by "vector processing" in claim 55.

53. With respect to examples 1 and 2, the specification does not explain how, or disclose an algorithm for, combining the information from equations 3, 4, 5, and 6, nor does the specification explain how, or disclose an algorithm for, performing the function of "calculating a further data set that describes the three dimensional shape and position of a segment of said neural tissue." Using these four equations separately does not perform the recited function and so is not clearly linked to the recited function.

54. With respect to examples 3 and 4 provided in Dr. Filler's report, the specification states that:

> Alternative forms of vector analysis can also be applied, for example, as described in Basser et al., Fiber Orientation Mapping in an Anisotropic Medium with NMR Diffusion Spectroscopy, SMRM BOOK OF ABSTRACTS 1221 (1992). Similarly, tensor analyses employing tensors of various ranks, as described in Basser et al., Diagonal and Off Diagonal Components of the Self-Diffusion Tensor: Their Relation to an Estimation from the NMR Spin-Echo Signal, SMRM BOOK OF ABSTRACTS 1222 (1992), can be used to treat, or transform the coordinates of, MR diffusional anisotropy data. ('360 patent 21:35-45.)

55. The cited statement from the specification is just an open-ended reference to the prior art work of Basser, et al. That reference to Dr. Basser's abstracts does not, however, by

itself convey to a person of skill in the art an algorithm or description of how to apply or implement Dr. Basser's work to accomplish the recited function in claims 58 or 61.

56. Further, Dr. Basser's abstracts do not describe "calculating a further data set that describes the three dimensional shape and position of a segment of said neural tissue by analyzing the data representative of anisotropic diffusion to determine how to relate said data set and said additional data sets describing the shape and position of cross sections of said neural tissue."

57. Further, Dr. Basser' abstracts do not describe "calculating a further data set that describes the three dimensional shape and position of a segment of said neural tissue by combining said data set and said additional data sets to generate said further data set that describes the three dimensional shape and position of the segment of said neural tissue."

58. With respect to example 5, the patent specification states that "suitable alternative processing techniques have been developed for use in the evaluation of magnetic, thermal, and structural anisotropy data." ('360 patent 21:45-47.) That statement does not convey any particular algorithm for "calculating a further data set that describes the three dimensional shape and position of a segment of said neural tissue" to one of ordinary skill in the art, and does not disclose the precise description for any specific algorithm for performing that function.

B. "excitation and output arrangement means" limitation in claim 54

59. Claim 54 of the '360 patent refers to an "excitation and output arrangement means" that performs the function of:

> exposing a region to a suppression sequence of electromagnetic fields that suppresses the electromagnetic responsiveness of structures in the region that do not exhibit diffusion anisotropy, so as to increase the apparent diffusion anisotropy of structures in the region that exhibit diffusion anisotropy, said suppression sequence of electromagnetic fields not including diffusion-weighted magnetic gradients

60. This function would be implemented, in part, by a computer programmed with a sequence of RF pulses designed to suppress the signal output from fat.

61. Plaintiffs appear to agree that this function would be implemented, in part, by a computer. Dr. Filler's report notes that computer 72 (along with excitation coil 62, RF pulse generator 84, and front-end circuit 74) is one of the structures necessary for performing this function. (Filler Report at ¶62; *see also* Filler Report ¶50 ("The pulse sequences, including the manipulation of the RF coils, output coils or antenna . . . are all controlled by one or more computers and front-end circuits.").) The specification discloses that the computer 72 is simply a computer, stating that it could be, "for example, an IBM-compatible personal computer including a 486 processor, VGA monitor, and keyboard." ('360 patent 11:15-17.)

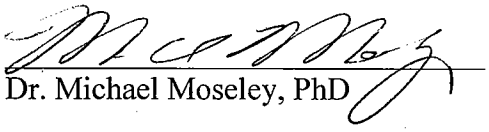
62. Dr. Filler's report also indicates that to achieve the recited function the computer would need to be programmed with a particular pulse sequence that suppresses the responsiveness of structures that do not exhibit diffusion anisotropy. (Filler Report ¶¶58, 59.)

63. Dr. Filler's report points to several portions of the specification that he believes show "examples" of pulse sequences that could be programmed into the computer to perform the recited function. Such a pulse sequence is, in my opinion, necessary to achieve the recited function. Disclosing simply that a computer could perform the recited function does not, by itself, convey a precise description to a person of skill in the art as to how the computer would perform this function. Rather, to convey to a person of skill in the art the limits of the claim, the specification would need to disclose and clearly link a particular pulse sequence that is programmed into computer 72 to perform this function recited in claim 54.

64. The only such pulse sequences Dr. Filler points to in his report as performing the recited function of the "excitation and output arrangement means" limitation are fat suppression

pulse sequences. (Filler Report ¶¶63-65.) And the only such pulse sequences for fat suppression disclosed in the specification are a CHESS method, the Dixon technique, and a STIR method. ('360 patent 13:7-40.) Thus, the necessary structure for performing the recited function of the excitation and output arrangement means limitation in claim 54 includes, not computer 72 by itself, but instead computer 72 programmed with the CHESS, Dixon technique, or STIR pulse sequences described at column 13, lines 7 through 40 of the patent.

Dated: February 2, 2011



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